



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3412-FN]

Medicare Program; Application by the American Diabetes Association (ADA) for Continued CMS Approval of its Diabetes Outpatient Self-Management Training Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final Notice.

SUMMARY: This final notice announces our decision to approve the American Diabetes Association (ADA) application for continued recognition as a national accrediting organization (AO) for accrediting entities that wish to furnish diabetes outpatient self-management training services to Medicare beneficiaries.

DATES: This final notice is effective on September 27, 2021 through September 27, 2027.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Diabetes outpatient self-management training services are defined at section 1861(qq)(1) of the Social Security Act (the Act) as “educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide

the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.”

In addition, section 1861(qq)(2)(A) of the Act describes a “certified provider” as a physician, or other individual or entity designated by the Secretary of the Department of Health and Human Services (the Secretary), that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title. Section 1861(qq)(2)(B) of the Act further specifies that a physician, or such other individual or entity, must meet the quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board or is recognized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

Section 1865 of the Act also permits the Secretary to use accrediting bodies to determine whether a provider entity meets Medicare regulatory quality standards, such as those established for diabetes outpatient self-management training programs. These accrediting bodies determine whether a diabetes outpatient self-management training supplier meets the Medicare regulatory quality standards established for diabetes outpatient self-management training service programs. A national accrediting organization (AO) must be approved by the Centers for Medicare & Medicaid Services (CMS) and meet the standards and requirements specified in 42 CFR part 410, subpart H, to qualify for Medicare deeming authority.

Our regulations regarding the application procedures for diabetes outpatient self-management training AOs seeking CMS approval are set forth at 42 CFR 410.142. A national accreditation organization applying for deeming authority must provide CMS with reasonable

assurance that it will require the diabetes outpatient self-management training suppliers it accredits to meet the CMS quality standards, the National Standards for Diabetes Self-Management Education and Support (NSDSMES) standards, or an alternative set of standards that meet or exceed our requirements that have been developed by that AO and that have been approved by CMS (see 42 CFR 410.144) .

Section 410.142(a) of our regulations states that “CMS may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training.” Therefore, all diabetes outpatient self-management training AOs must be not-for-profit organizations.

Section 410.142(b) of our regulations require a diabetes outpatient self-management training AO to submit specific documents and information with their application, as discussed in section II of this final notice.

II. Provisions of the Proposed Notice

On April 27, 2021, we published a proposed notice in the **Federal Register** (86 FR 22211) acknowledging receipt of the American Diabetes Association’s (ADA’s) request for continued CMS approval of its diabetes outpatient self-management training accreditation program. In that proposed notice, we detailed our evaluation criteria.

Under section 1861(qq) of the Act and our regulations at § 410.142, we conducted a review of the ADA’s diabetes outpatient self-management training program application using the criteria specified by our regulations, which include authorization for CMS to conduct an onsite visit to verify information in the organization’s application. For an onsite visit, the CMS review team travels to the AO’s corporate office to review specific information and documents. An onsite visit is typically part of every application review. However, due to the COVID-19 pandemic, it was not possible for us to conduct an onsite visit for the ADCES. We conducted our review virtually, using remote means to access and review the necessary information. During this virtual review, we reviewed documentation including the ADA’s: (1) corporate

policies; (2) financial and human resources records; (3) policies and procedures, including those for training, monitoring, and evaluation of its surveyors and investigating and responding appropriately to complaints against accredited diabetes outpatient self-management training suppliers; and (4) survey review and decision-making process for accreditation. This is the same information that would have been reviewed during an onsite visit.

Also, as part of the ADA's application review, we reviewed and assessed the following documents submitted by the ADA:

- A detailed comparison including a crosswalk between the organization's standards and the CMS quality standards described in § 410.144(a).
- Detailed information about the organization's accreditation process, including all of the following information:
 - ++ Frequency of accreditation.
 - ++ Copies of accreditation forms, guidelines, and instructions to evaluators.
 - ++ Descriptions of the following:
 - The accreditation review process and the accreditation status decision making process.
 - The procedures used to notify a deemed entity of deficiencies in its diabetes outpatient self-management training program and procedures to monitor the correction of those deficiencies.
 - The procedures used to enforce compliance with the accreditation requirements and standards.
- Detailed information about the individuals who perform evaluations for the organization, including all of the following information:
 - ++ The education and experience requirements for the individuals who perform evaluations.
 - ++ The content and frequency of continuing education furnished to the

individuals who perform evaluations.

++ The process used to monitor the performance of individuals who perform evaluations.

++ The organization's policies and practices for participation in the accreditation process by an individual who is professionally or financially affiliated with the entity being evaluated.

- A description of the organization's data management and analysis system for its accreditation activities and decisions, including the kinds of reports, tables, and other displays generated by that system.
- A description of the organization's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.
- A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.
- A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.
- A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.
- The name and address of each person with an ownership or control interest in the organization.

- Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.
- A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.
- A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§ 410.142 through 410.146.
- Any additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

The April 27, 2021, proposed notice also solicited public comment regarding whether the ADA's requirements meet or exceed the NSDSMES, which are the accreditation standards used for accreditation of diabetes outpatient self-management training programs accredited by the ADA, pursuant to § 410.144(b) and § 410.142(e)(1).

III. Analysis of and Responses to Public Comments on the Proposed Notice

CMS received three comments in response to the April 27, 2021 proposed notice; however, only one of these comments were within the scope of the comment solicitation.

The comment and our response is addressed below.

Comment: One commenter stated that diabetes outpatient self-management training, also sometimes referred to as diabetes self-management education and support is an evidence-based vital service for people who have been diagnosed with diabetes, that has been proven to enhance their clinical outcomes. The commenter also stated “wholehearted” support for the application submitted by the ADA for continued CMS recognition as a national AO for diabetes outpatient self-management training programs. The commenter further stated the belief that “it is imperative that the ADA continue to offer its services as an AO for outpatient self-management training suppliers.”

Response: We thank the commenter for their support of the CMS diabetes outpatient self-management training program and for their recommendation for the approval of the ADA's application.

IV. Provisions of the Final Notice

A. Comparison of the ADA's Standards and Requirements for Accreditation to the NSDSMES and the Medicare Application Requirements

We compared the ADA's diabetes outpatient self-management training accreditation requirements and survey process with the NSDSMES requirements and CMS application requirements in 42 CFR part 410, subpart H, as described in section II of this final notice.

We found the ADA's accreditation standards and process to be consistent with the NSDSMES standards and CMS requirements.

B. Term of Approval

Based on the review and observations described in section II of this final notice, we have determined that the ADA's requirements for diabetes outpatient self-management training meet our requirements. Therefore, we approve the ADA as a national accreditation organization for diabetes outpatient self-management training program that request participation in the Medicare program, effective September 27 2021 through September 27, 2027.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 22, 2021.

Lynette Wilson,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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